

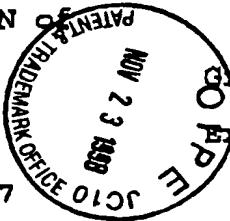
## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

BOUCHARD, et al.

Appln. No.: 08/786,937

Filed: January 22, 1997

FOR: LHRH-ANTAGONISTS IN THE  
TREATMENT OF FERTILITY DISORDERS

Group Art Unit: 1811

Examiner: Delacroix-Muirheid

## DECLARATION

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

We, Philippe Bouchard, René Frydman, Paul Devroey, Klaus Diedrich, and Jürgen Engel hereby declare and state as follows:

1. We are the named Inventors on Patent Application No. 08/786,937 and are familiar with the prosecution history of the application including the Office Actions of December 1, 1997 and June 22, 1998, and the Amendment filed on April 1, 1998, adding new claims 15-32.

2. In the aforementioned Office Actions, claims 1-14 (now canceled) and new claims 15-32 were rejected under 35 U.S.C. § 103 as allegedly being obvious over Diedrich et al. (Human Reproduction 9(5): 788-791, 1994) in combination with Felberbaum et al. (European Journal of Obstetrics and Gynecology and Reproductive Biology 61:151-155, 1995). It was the Examiner's position that Diedrich et al. disclose a method of inducing ovarian stimulation in tubal sterile patients by

BOUCHARD et al. -- Appln. No.: 08/1786,937

administering a combination of exogenous gonadotrophins and the LHRH antagonist Cetrorelix to said patients, and that Felberbaum et al. teaches treating women with tubal infertility with a combination of exogenous gonadotropins and Cetrorelix and a specific dosage regimen. It was the Examiner's opinion that it would have been obvious to combine the teaching of Diedrich et al. with that of Felberbaum et al. to result in the present invention because Felberbaum et al. discloses that ovarian stimulation is induced, and furthermore teaches that the disclosed treatment would be effective in the treatment of Polycystic Ovary Disease.

3. We are the inventors of the subject matter disclosed in European Journal of Obstetrics and Gynecology and Reproductive Biology 61:151-155, which the Examiner has indicated can be combined with Diedrich et al. to produce the invention claimed in claims 1-14 and 15-32. Specifically, we are the original inventors of the disclosure by this reference that ovarian stimulation is induced by the combination hMG/Cetrorelix, and that treatment with this combination would be effective in the treatment of Polycystic Ovary Disease. The study described in the reference were directed by Klaus Diedrich as a direct result of his knowledge of the present invention, which resulted from a collaborative effort between Klaus Diedrich and the other named inventors.

P 384  
Contract of  
Inventors

4. Named coinventors of the present application Philippe Bouchard, Rene Frydman, Paul Devroey, and Jürgen Engel are not

**BOUCHARD et al. -- Appln. No.: 08/786,937**

*To whom  
this particular  
study refers*

listed as coauthors on the reference because they were not directly involved in carrying out this particular study.

5. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Date: 2.10.98  
 Date: 21.9.98  
 Date: 5.10.98  
 Date: 6.10.98  
 Date: 6.10.98

By: *Philippe Bouchard*  
 By: *Philippe Bouchard*  
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